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|--|-------------|----------------------|---------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/528,229   | 03/18/2005  | Daisuke Itoh         | 2005_0470A          | 6230             |
| 513  | 7590        | 11/10/2009           |                     |                  |
| WENDEROTH, LIND & PONACK, L.L.P.<br>1030 15th Street, N.W.,<br>Suite 400 East<br>Washington, DC 20005-1503 |             |                      | EXAMINER            |                  |
|  |             |                      | WOOD, ELLEN S       |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1794                |                  |
|  |             |                      |                     |                  |
|  |             |                      | MAIL DATE           | DELIVERY MODE    |
|  |             |                      | 11/10/2009          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                    |
|------------------------------|--------------------------------------|------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/528,229 | <b>Applicant(s)</b><br>ITOH ET AL. |
|                              | <b>Examiner</b><br>ELLEN S. WOOD     | <b>Art Unit</b><br>1794            |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 October 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7 and 9-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/GS-68)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/20/2009 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-7 and 9-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shiiki et al. (EP0925915, hereinafter "Shiiki").

In regards to claims 1-7, Shiiki discloses a gas barrier multi-layer hollow container with a polyglycolic acid layer [0028]. The polyglycolic acid useful is a polymer containing a repeating unit represented by the following formula (1):



This is the formula of the instant applicant's recurring unit of the glycolic acid polymer (pg. 7 lines 19-23). Shiiki discloses that the crystalline aliphatic polyester is glycolic acid homopolymer [0031]. The blow molding process to make the hollow container includes a stretch blow molding process [0052]. Thus, the container has a layer that is a stretched product of crystalline aliphatic polyester.

In regards to claims 9, Shiiki discloses that the aliphatic polyester layer is comprised of a glycolic acid homopolymer [0065 and table 1].

In regards to claim 10, Shiiki discloses that the multi-layer hollow container has a layer of polyglycolic acid [0013], thus the polyglycolic acid is in the form of a film.

In regards to claim 11, Shiiki discloses that the polyglycolic acid is a layer of a hollow container [0013], thus in the form a bottle.

In regards to claim 12, Shiiki discloses that various thermoplastic resin layers (polymer layer) may be laminated to the polyglycolic acid layer [0019-0020].

Shiiki does not disclose that the aliphatic polyester has a crystal melting point higher by at least 3°C and 5°C than that of an un-stretched product, the sub-dispersion peak temperature, the main dispersion peak temperature and the orientation degree measured by wide-angle X-ray diffractometry.

Shiiki discloses that when the T<sub>m</sub> of the polyglycolic acid is lowered, the processing temperature of the polymer can be lowered, therefore thermal decomposition upon melt processing can be reduced [0031]. The crystallization rate of the polyglycolic acid can also be controlled by copolymerization to improve its extrudability and stretchability [0031]. Shiiki discloses that the "stretch blow molding process" is a process in which stretching is conducted upon blow molding, thereby orienting the molecular chain of a polymer to enhance the physical properties of the polymer such as transparency, strength, elastic modulus and gas barrier properties [0052]. In order to enhance such physical properties, it is essential to keep a parison at a temperature not higher than its melting point, but not lower than its glass transition point upon stretch blow molding [0052]. The composition of the polyglycolic acid layer and the crystalline aliphatic polyester disclosed by applicant are substantially similar in structure and chemical composition (see pgs. 6-12 of applicant's specification). Products of identical structure and composition cannot have mutually exclusive properties. The burden is on the Applicants to prove otherwise.

It would be obvious to one of ordinary skill in the art at the time of the invention that the physical properties of the polyglycolic acid layer as disclosed in Shiiki would be enhanced due to the orientation of the molecular chain of the polymer by intense stretching [0052].

***Response to Arguments***

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5. Applicant's arguments filed 10/20/2009 have been fully considered but they are not persuasive.

6. The applicant argues that there is no reason to believe that the physical properties enhanced by stretching taught by Shiiki et al. include an elevated crystal melting point, because stretching is basically known as a process acting on the amorphous portion, and not on the crystalline portion of a polymer.

In response, the declaration submitted by applicant on 09/26/2008 states that the invention of the instant application is based on the discovery that only intense stretching, i.e., at a large stretching ratio and at a temperature not substantially higher than a glass transition temperature of a crystalline aliphatic polyester, results in the characteristic effects of the instant invention (pg. 2 #6). The intense stretching effects could only be attained by stretching at a large ratio exceeding 3x3 times and at temperatures of which are not substantially above the glass transition temperature but much lower than the melting point of PGA (pg. 2 #6). Thus, according to applicants statements submitted in the declaration it would be clear to one of ordinary skill in the art that stretching is not only a process acting on the amorphous portion but also on the crystalline portion of the polymer, thus enhancing physical properties.

Shiiki discloses that the "stretch blow molding process" is a process in which stretching is conducted upon blow molding, thereby orienting the molecular chain of a polymer to enhance the physical properties of the polymer such as transparency, strength, elastic modulus and gas barrier properties [0052]. In order to enhance such physical properties, it is essential to keep a parison at a temperature not higher than its

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melting point, but not lower than its glass transition point upon stretch blow molding [0052]. Thus, Shiiki discloses a substantially similar stretching process as that of the applicant, wherein the stretching is conducted at a specific temperature that is not substantially higher than the glass transition temperature of the crystalline aliphatic polyester but not higher than its melting point. This process and the composition of the crystalline aliphatic polyester as disclosed by Shiiki are substantially similar to that of the applicant, thus it would be inherent that that the stretched product of crystalline aliphatic polyester would have the physical properties claimed by applicant.

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference.

7. The applicant argues that Shiiki does not disclose a glycolic acid homopolymer

In response, Shiiki discloses that the crystalline aliphatic polyester is glycolic acid homopolymer [0031].

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLEN S. WOOD whose telephone number is (571)270-3450. The examiner can normally be reached on M-F 730-5 with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rena L. Dye/  
Supervisory Patent Examiner, Art Unit 1794